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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,809	04/09/2004	Irving W. Wainer	1173-1025PUS2	9486

33883 7590 01/29/2008
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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01/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,809

Applicant(s)

WAINER ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) 11-13, 18, 19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10, 17, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Amendment filed 11/21/2007 is acknowledged. Claims 21-25 are added. Claims 8-13, 17-25 are currently pending.

Claims 11-13, 18, 19, remain withdrawn from consideration. Consequently, claims 24, 25, which are dependent on claim 19, are also withdrawn from consideration.

2. Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Original claims specifically require methyl group connected to nitrogen of dextromethorphan to be substituted with alkyl group bearing a nitrogen-containing heterocycle group. The compounds of claim 21 are not included in the scope of the above compounds as they clearly do not have said methyl group substituted with alkyl group bearing a nitrogen-containing heterocycle group. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

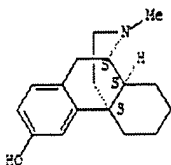
3. Applicant's arguments were considered and deemed persuasive-in-part.

Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102 and 103.

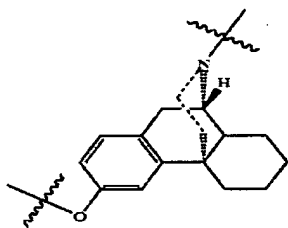
4. Claims 8,9,17 are rejected under 35 U.S.C. 102(e) as clearly anticipated by Wu et al (US 2005107415 A1; priority date 05/17/2002).

The claims, to the extent of the elected species are directed to dextromethorphan having methyl group substituted by alkyl group bearing a nitrogen-containing heterocyclic group. Dextromethorphan is a compound of formula

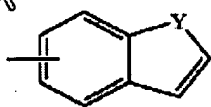


(Registry Number 125-73-5)

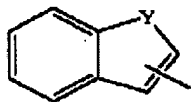
Wu et al teach derivatives of compound RAX, wherein R can be H, A is of formula VII, X is $(CH_2)_n - R_5$, R_5 is heterocycle of formula IX or X, with $Y=N$. See p. 3-4. The same subject matter is addressed in the priority application, 60/518488 – see p. 11-13.



(vii)



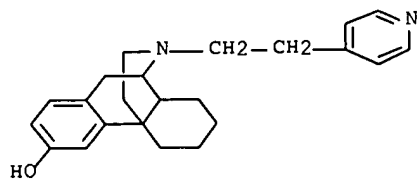
IX



X

5. Claims 8,9,17 are rejected under 35 U.S.C. 102(b) as clearly anticipated by Grussner et al (US 2970147).

Grussner teaches morphinan derivatives, such as 2H-10,4a-Iminoethanophenanthren-6-ol, 1,3,4,9,10,10a-hexahydro-11-[2-(4-pyridyl)ethyl]- (Registry Number 820985-88-4) of the formula



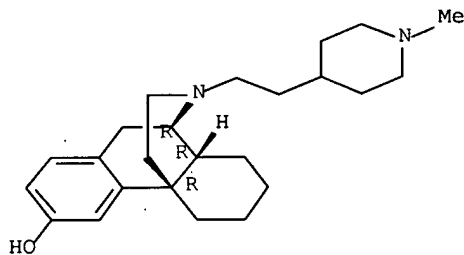
Response to argument

Applicant's argument that "Grussner '147 does not disclose dextromethorphan derivatives; the 3 carbon is substituted by a hydroxyl, not a methoxyl, group." is not well taken: the instant claims, while indeed claiming dextromethorphan derivatives are silent about presence or absence of any modifications at the 3 carbon position.

Further, in regard to argument that the referenced compound does not have the functionality as inhibitor of ligand-gated channels, the instant claims do not recite any functional limitations.

6. Claims 8-10,17 are rejected under 35 U.S.C. 102(b) as clearly anticipated by Eddy et al (Bull Narcotics, U.N., Dept. Social Affairs, 1958, 10(No. 4), 23-41). See Abstract in Database HCAPlus, 53:95845.

The reference teaches compound



i.e., a compound as claimed wherein "nitrogen-containing heterocyclic group" is piperidine.

7. Claims 22,23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wu et al, or Grussner et al, or Eddy et al. The references are applied as addressed above.

The references teach the products that meet the structural limitation claimed. Although the references do not teach the functional limitation of the product, such a limitation would be inherent in the product, since it meets the structural limitations of the claim. A reference which is silent about a claimed invention's feature is inherently anticipatory if the missing feature is necessarily present in that which is described in the reference. In re Oelrich, 212, USPQ 323 (CCPA 1981).

It has been held that where applicant claims a product in terms of function, property or characteristic where said function is not explicitly shown by the reference and where the examiner has explained why the function, property or characteristic is considered inherent in the prior art, it is appropriate for the examiner to make a rejection under both the applicable section of 35 USC 102 and 35 USC 103 such that the burden is placed upon the applicant to provide clear evidence that the respective compositions do in fact differ. *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Fitzgerald et al*, 205 USPQ 594.

A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure and composition, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Where the claimed and prior art products are identical or substantially identical in composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

8. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.
Primary Examiner